REMARKS

Entry of this amendment is respectfully requested.

Claims 1, 3-29 and 33-40 are in the application. Through this amendment, claims 1 and 19 have been amended to more particularly point out and distinctly claim the invention of the subject application, whereas, claims 30-32 have been cancelled.

In the Official Action, the Examiner rejected claims 1, 3-18, 33, 34, 37 and 38 under 35 U.S.C. §102(a) as being anticipated by Lawecki et al. (U.S. Patent No. 5,687,542). This rejection was previously applied in an Office Action dated June 18, 2002 and responded to in an Amendment dated November 18, 2002. In response to Applicants' previous arguments, the Examiner stated in the present Office Action that Applicants' arguments have been fully considered but are not persuasive. Specifically, the Examiner stated:

> Applicants contend that Lawecki fails to teach or suggest enclosing the container in a second container and sterilizing the container and thus does not anticipate claim 1 as amended. This is not found persuasive because Lawecki does disclose the step of sterilizing the container (col. 3, line 43-48) and thus anticipates the claimed invention as recited in the amended claim 1.
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> Applicants further contend that Lawecki does not teach or suggest the step of delivering a tip cap to the environmentally controlled area and air cleaning the tip cap in the environmentally controlled area as recited in claims 33 and 37. This is not found persuasive because the method of Lawecki utilizes laminar stream of air flow

> to clean fabricated articles including the syringes and/or tip seals that are introduced into the enclosure (10) of class 100 environment.
>
> Regarding the traversal with respect to claim 19, although neither Lawecki nor Logothetis expressly discloses annealing a glass syringe barrel at a temperature of at least 500°C, the specific annealing temperature is well within the knowledge of a skilled person in the art, and therefore it would have been obvious to a person with an ordinary skill in the art, at the time the invention was made, to have annealed the glass syringes barrel at a temperature of at least 500°C.

Lawecki et al. is directed to an apparatus for manufacturing articles, such as syringe barrels, substantially free from contaminants. Specifically, Lawecki et al. discloses an enclosure 10 which includes two main components, a molding isolation module 12 and a packaging isolation module 14. An injection molding machine 18 is connected to the molding isolation module 12. Lawecki et al. specifically discloses to form the article, such as by molding, with sufficient heat to render the molded article substantially free from contaminants. (Column 1, lines 53-58; column 3, lines 35-41). If insufficient heat is provided, internal surfaces of the molding isolation module 12 are periodically sterilized, such as with sterilizing gas or vapor. (Column 3, lines 43-48; column 8, lines 30-45). To prevent contaminants from settling on the clean surfaces of the molded articles, laminar air flow is provided to the molding isolation module 12. (Column 4, lines 23-25). The molded articles are transferred from the molding isolation module 12 to the packaging isolation module 14 which also includes laminar air flow.

(Column 2, lines 18-20; column 6, lines 49-51). It is clear from the teaching of Lawecki et al. that Lawecki et al. seeks to form a product free of contaminants, either by providing sufficient heat at the time of formation or by using sterilization, and to provide sufficient air flow thereafter to prevent contaminants from settling on the clean surfaces of the formed products.

Claim 1, as amended, clearly indicates that the container is sterilized only after it is wholly enclosed in a second container. As indicated above, Lawecki et al. discloses the step of sterilizing the container but only at the time of product formation. Lawecki et al. specifically discloses the use of laminar air flow to prevent contaminants from settling onto the product thereafter. There is no disclosure or suggestion in Lawecki et al. to sterilize an article at a point after molding, particularly after packaging the article in a second container. As such, it is respectfully submitted that claim 1, along with dependent claims 3-18, are patentable over Lawecki et al.

Both claims 33 and 37 include the steps of "delivering a tip cap to said environmentally controlled area" and "air cleaning said tip cap in said environmentally controlled area". As indicated above, the Examiner asserted that "Lawecki utilizes laminar stream of air flow to clean fabricated articles including the syringes and/or tip seals that are introduced into the enclosure (10)". Applicants respectfully traverse this assertion. With reference to Lawecki et al., any

additional articles to be assembled with the syringe barrels are to be formed in secondary molding isolation modules, such as second molding isolation module 212. Within the principles of Lawecki et al. indicated above, the additional articles are to be either prepared with sufficient heat to be contaminant-free or be prepared under some form of sterilization medium. (Column 8, lines 1-18). Tip seals are referred to in only one place in Lawecki et al., namely column 8, line 25. As stated therein, "intermediate module 250 may be used for applying a lubricant, such as silicone oil, to the manufactured articles, for example, the inner barrel surfaces...or...tip seals (not shown)." It is clear from this statement that tip seals are intended to be considered manufactured articles in Lawecki et al. Accordingly, Lawecki et al. seeks to form tip seals clean within the system, and maintain that cleanliness. There is no disclosure or suggestion in Lawecki et al. to air clean tip caps, since the tip caps are formed and maintained clean in the system. It is respectfully submitted that claims 33 and 37, along with dependent claims 34 and 38, respectively, are patentable over Lawecki et al.

Claims 3, 10 and 11 were alternatively rejected under 35 U.S.C. §103(a) as being obvious over Lawecki et al. in view of Logothetis (U.S. Patent No. 4,521,237). The Examiner relied upon Logothetis for disclosing a method of forming a glass syringe barrel.

Logothetis is directed to a disposable, single-use, medication syringe having a glass barrel. Logothetis is only concerned with the construction of the syringe and provides no detail as to the packaging thereof. As such, Logothetis does not overcome the deficiencies of Lawecki et al. noted above in conjunction with the discussion of claim 1. It is respectfully submitted that claims 3, 10 and 11, as depending from claim 1, are patentable over Lawecki et al. and Logothetis, each taken alone or in combination.

Claims 7, 15 and 33 were alternatively rejected under 35 U.S.C. §103(a) as being obvious over Lawecki et al. in view of Jurgens, Jr. et al. (U.S. Patent No. 4,628,969). The Examiner relied on Jurgens, Jr. et al. to disclose a process for lubricating and filling a syringe.

Jurgens, Jr. et al. is directed to a method of producing pre-filled sterile plastic syringes. The Jurgens, Jr. et al. method specifically calls for sterilizing (step 92 of autoclaving) the assembled syringe prior to packaging (step 96). Accordingly, there is no disclosure or suggestion in Jurgens, Jr. et al. to package a container into a second container and then sterilize the container, as called for in claim 1. Accordingly, Jurgens, Jr. et al. does not overcome the deficiencies of Lawecki et al. noted above with respect to claim 1. It is respectfully submitted that claims 7 and 15, as both depending from claim 1, are patentable over Lawecki et al. and Jurgens, Jr. et al., each taken alone or in combination.

With respect to claim 33, Jurgens, Jr. et al. specifically calls for sterilizing tip seals (step 72 of autoclaving) prior to assembling the tip seals with syringe barrels. However, it would be improper to modify Lawecki et al. to include such an autoclaving step, since this hypothetical change would improperly alter the principle of operation of Lawecki et al. M.P.E.P. §2143.02. In particular, Lawecki et al. specifically calls for clean formation of components under sufficient heat or through sterilization, and for maintaining a continuous laminar air flow about the molded articles to keep contaminants off the surfaces thereof. There is no motivation to include a step of autoclaving in Lawecki et al. Moreover, Lawecki et al. specifically discusses Jurgens, Jr. et al. in its background section and rejects the Jurgens, Jr. et al. method as being dependent on the steps of cleaning articles to eliminate contamination. (Column 1, lines 14-35). Lawecki et al. specifically avoids the cleaning steps required in Jurgens, Jr. et al. It is respectfully submitted that claim 33 is patentable over Lawecki et al. and Jurgens, Jr. et al., each taken alone or in combination.

Claim 37 was rejected under 35 U.S.C. §103(a) as being obvious over Lawecki et al. in view of Smith et al. (U.S. Patent No. 5,597,530).

Smith et al. is directed to a method of filling syringes which includes a luer cap 14 which is cleaned before being assembled to the syringe barrel 12, but is not considered sterile in that

assembled state. (Column 5, lines 55-60). The entire assembled syringe is sterilized, once filled. (Column 6, lines 37-44). Accordingly, Smith et al. does not overcome the deficiencies of Lawecki et al. noted above with respect to claim 37. Smith et al. does not provide maintained sterilization of a component, but instead relies on sterilization of a complete assembly. There is no motivation or suggestion to combine Lawecki et al. and Smith et al., since Lawecki et al. relies upon a completely different principle for obtaining sterile assemblies: components are manufactured initially clean, and contamination is avoided until full assembly is achieved. Smith et al. relies on sterilization of a complete assembly. The operating principle of Lawecki et al. is completely different from the operating principle of Smith et al. and the two cannot be combined. It is respectfully submitted that claim 37 is patentable over Lawecki et al. and Smith et al., each taken alone or in combination.

Claims 19-32 were rejected under 35 U.S.C. §103(a) as being unpatentable over Lawecki et al. in view of Logothetis. The Examiner asserted that Lawecki et al. discloses all of the claimed subject matter "except for the detailed process of forming a glass syringe" and relied on Logothetis to overcome this deficiency.

Claim 19 includes the steps of forming, annealing, and then "immediately transferring said syringe barrels to at least one housing assembly for maintaining a predetermined cleanliness

level." With the invention of claim 19, the glass syringe barrels are transferred to a housing assembly for maintaining cleanliness after annealing. In Lawecki et al., laminar air flow is continuously directed towards the mold cavity (column 5, lines 28-67). Lawecki et al. requires its laminar air flow to reach the mold cavity and to be present in all parts of the apparatus, including any intervening stages. In combining Logothetis with Lawecki et al., the hypothetical combination would yield an apparatus having an annealing stage inserted between the molding stage and further processing; however, the annealing stage would be inside the housing and subjected to laminar air flow to maintain the desired cleanliness level. In contrast, claim 19 calls for forming, annealing and then transferring the molded articles to a housing for maintaining a predetermined cleanliness level. The forming and annealing steps can be performed outside the housing for maintaining cleanliness. It is respectfully submitted that claim 19, along with dependent claims 20-29, are patentable over Lawecki et al. and Logothetis, each taken alone or in combination.

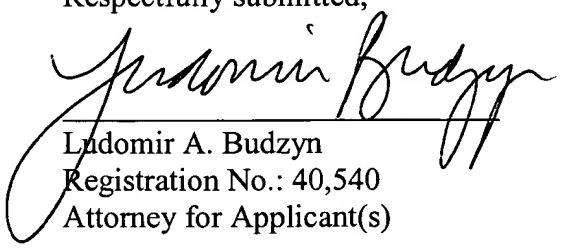
Claims 35 and 36 were rejected under 35 U.S.C. §103(a) as being unpatentable over Lawecki et al. in view of Jurgens, Jr. et al. Claims 35 and 36 depend from claim 33 which was rejected based on this same hypothetical combination. For the reasons stated above with respect to claim 33, it is respectfully submitted that claims 35 and 36, as depending from claim 33, are also patentable.

Claims 39 and 40 were rejected under 35 U.S.C. §103(a) as being unpatentable over Lawecki et al. in view of Smith et al. Claims 39 and 40 depend from claim 37, which was rejected on this same basis. For the reasons stated above with respect to claim 37, it is respectfully submitted that claims 39 and 40, as depending from claim 37, are also patentable.

For the record, attached hereto is an Appointment of Associate Attorney granting the undersigned authority to act in this application. In addition, the form includes a change of correspondence address. It is respectfully requested that the PTO update its records to direct correspondence as indicated therein.

Favorable action is earnestly solicited. If there are any questions or if additional information is required, the Examiner is respectfully requested to contact Applicants' attorney at the number listed below.

Respectfully submitted,



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VERSION OF AMENDMENT WITH MARKINGS SHOWING CHANGES MADE

IN THE CLAIMS:

1. (Twice Amended) A method producing a container comprising the steps of:

forming a container in a forming device,

transferring said container to an environmentally controlled area to maintain a predetermined cleanliness level,

cleaning said container,

enclosing wholly said container in a second container, [and]then

sterilizing said container.

19. (Amended) A method of producing prefillable glass syringe barrel assemblies comprising the steps of:

forming a plurality of clean syringe barrels in a glass forming device for shaping a cylindrical glass tube into syringe barrels having a first open end for receiving a syringe plunger and a second open end for discharging contents from said syringe barrels;

annealing said glass syringe barrels at a temperature of at least 500°C; [and]then,

immediately transferring said syringe barrels to at least one housing assembly for maintaining a predetermined cleanliness level.